DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 3, 2014

RADIOLOGY SOLUTIONS LLC
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associate
8870 Ravello Court
NAPLES FL 34114

Re: K141743
Trade/Device Name: Fusion Digital Diagnostic X-ray Upgrade Kit
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 1, 2014
Received: September 4, 2014

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141743

Device Name
FUSION DIGITAL X-RAY DETECTOR (upgrade kit)

Indications for Use *(Describe)*
This flat panel digital imaging system is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. This device is intended for use by qualified medical personnel. (Not for mammography)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary – K141743

1. Submitter:
RADIOLOGY SOLUTIONS LLC
1912 Golfcrest Dr
Commerce Twp, MI 48382
Tel. 866.681.6681
Date Prepared: September 19, 2014
Contact: Scott Milgrom, President

2. Identification of the Device: Fusion Digital Diagnostic X-Ray Upgrade Kit.
Classification Name: Stationary X-ray system
Common/Usual Name: Digital X-ray Panel (upgrade kit)
Regulation Numbers: 21 CFR 892.1680; Product Code: MQB

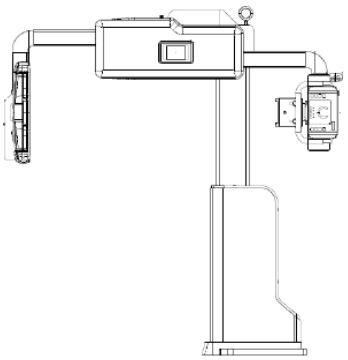
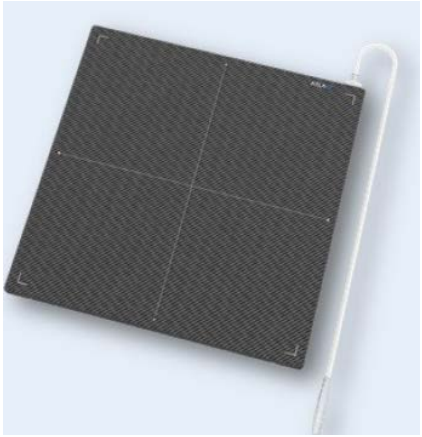
3. Predicate Device: Fusion Digital Diagnostic X-Ray Upgrade Kit uses the IDENTICAL digital x-ray panel/software/workstation that was cleared in K132294. The only difference is the generator and tubestand is not supplied.

4. A description of the device: This is a digital x-ray panel coupled with image acquisition software. The acquisition software is installed on a Windows compatible workstation. No routine user calibration or generator connection is required. Problems which ensue when system is depended upon for timing…the most crucial part in the digital Image creation… are eliminated. These are the vast majority of service issues in DR retrofits. AED and ACC are standard features. AED is automatic exposure detection. No synchronization connection to the generator is required. ACC is Automatic Calibration Control. Calibration values are automatically loaded at power-up. The TFT is inherently linear, and all that is necessary is to set a Start (Dark) and Stop (Bright) value to define the dynamic range you want to operate in. It is completely independent of the x-ray source. That is why this can be done at the factory. MECHANICAL: FITS IN THE BUCKY TRAY WITHOUT MODIFICATION… Ultra-Light Cassette Sized Detector easily moves from table to table top to wall to stretcher with ease. The system is compatible with CPI CMP 200 and Sedecal SHF series generators. Testing has not been conducted regarding compatibility with other generators.

5. Intended use of the device: This flat panel digital imaging system is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. This device is intended for use by qualified medical personnel. (Not for mammography)

6. The Galaxy and Galaxy Plus have essentially the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device Sedecal. See the comparison table below. There are really only a few main differences: The digital panels, x-ray generator, and tube stands are from different manufacturers but with functionally identical capabilities.

Comparison Table

Characteristic	Galaxy and Galaxy+ Plus K132294	Fusion Digital Diagnostic X-Ray Upgrade Kit.
Indications	Intended for use by a qualified/trained doctor or technician on subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography)	This flat panel digital imaging system is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. This device is intended for use by qualified medical personnel. (Not for mammography)
Digital Receptor Panel	Atlaim ATAL 8 AND ATAL 8C (Cleared in K113812) to be known as "IRIS" AND "IRIS C"	SAME
Panel Communication	Tethered Ethernet, one panel	SAME
Panel Resolution	Pixel size 139 x 139 µm Image matrix size 3072 x 3072 pixels Number of pixels Approx. 9.4 million pixels	SAME
DICOM	Yes (Same software as cleared in K112527) to be known as "Nexxus"	SAME
Tube Stand	Same	NOT SUPPLIED
Generator	CPI, 40-50-65-or 80 kW (High Frequency)	NOT SUPPLIED but compatible with CPI CMP 200 and Sedecal SHF series generators.
Photo	Galaxy+ Plus 	

7. Description of non-clinical tests. No new testing was done because no modifications have been made other than deleting the generator and tube stand.

8. Description of clinical tests. No new testing was done because no modifications have been made other than deleting the generator and tube stand.

9. Conclusions drawn: The nonclinical and clinical tests performed in our previous clearance demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device that was our original predicate. Installation of the upgrade kit must be done by a qualified service technician and performance should be verified by the facility radiation physicist.